

ARIZONA DEPARTMENT OF HEALTH SERVICES	LEVEL	SECTION	NUMBER	DATE
	IV	ASTR	001	08/28/08
SUBJECT:	RELEASE OF TRAUMA REGISTRY DATA AND INFORMATION			

SUPERSESSON:	NONE
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PURPOSE

To set the standards for providing quality trauma data to health professionals, researchers and the general public from the Arizona State Trauma Registry (ASTR) while preserving confidentiality and protecting patient privacy of trauma cases reported to the ASTR. This Policy creates the procedure to release both confidential and non-confidential information.

POLICY

All requests for data will be evaluated and fulfilled according to the procedures described herein, and the policies set forth by governing agencies.

AUTHORITY

A.R.S. § 36-2221, Requirements: confidentiality: violation: classification.

APPLICABILITY

Arizona State Trauma Registry

Bureau of Emergency Medical Services and Trauma System

DEFINITIONS

Confidential data and information – Any form of data (case reports, computer records, computer printouts, etc.) that can be attributed to an individual patient or the patient’s family that is not considered public information.

Data Linkage – Process whereby it is determined if a record in a file matches to one or several records in another file.

Public Use Data Files – Data set available to the public with permission.

Researcher – Individual or group that is requesting confidential data from the Arizona State Trauma Registry (ASTR). This may include, but is not limited to, entities such as research groups, educational institutions, and government agencies.

Summary data and information – Data that is aggregated and displayed so that the individual patient or the patient’s family cannot be identified.

DIVISION OF PRIMARY RESPONSIBILITY

Bureau of Emergency Medical Services and Trauma System (BEMSTS)

PROVISIONS AND GUIDELINES

A. General Data Confidentiality Policies

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1. Confidential information shall not under any circumstances be published or made available to the general public.
2. Information on confidential data can be released for statistical purposes in a manner such that no individual patient or the patient's family can be identified.

B. Request for Confidential Data

1. Confidential data and information required by Researchers for research purposes will be released only upon approval of the BEMSTS Chief, BEMSTS Medical Director, BEMSTS Data & QA Section Chief, BEMSTS Trauma Section Chief, and Trauma Registry Manager. Researchers seeking information must submit a request to the ASTR in writing in accordance with established procedures as outlined in Procedure B.
2. Inquiries from the press/media shall be referred to the ADHS Public Information Office (PIO). The PIO can be contacted at (602)542-1094. Only aggregate non-confidential information may be given to the media but the BEMSTS Data & QA Section Chief must first inform the PIO of the inquiry.

C. Inappropriate Uses of Confidential Data or Information

1. ASTR data shall not be made available to the following:
 - a. Businesses trying to market a product to trauma patients
 - b. Insurance companies trying to determine the medical status of a patient
 - c. Next-of-kin of reported patients, without proper authorization

D. Disclosure of Summary Data

1. Summary data shall be disclosed in the following manner:
 - a. Summary data contained in published reports by ASTR will be available upon request.
 - b. Requests for summary data and information not available in ASTR reports must be made to the BEMSTS Data & QA Section Chief, the BEMSTS Trauma Section Chief or the Trauma Registry Manager. The requestor may be required to cover the costs of obtaining the data.
 - c. A comment, analysis, or interpretation of the data may be provided by the ASTR.
2. In order to eliminate the possibility that individuals might be identifiable from tables containing cells with very small values, cell counts may be suppressed in the case of tables with cell counts less than 5 for ≤ 1 year of data if the geographic area is smaller than the county level.
3. Users of ASTR Public-Use Data Files will be required to sign an ASTR Public-Use Data Agreement prohibiting the use of data for purposes of patient identification or for statistical publications that may result in the identification of a patient or the patient's family. These stipulations are outlined in further detail in the agreement. See Exhibit 1.

E. Re-Disclosure of Data

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1. Authorized recipients of confidential data and information shall not further disclose the data and information to any other person or organization.

F. Releasing Confidential Data to Other ADHS Programs

1. Confidential data may be released to another ADHS program upon completion of the ADHS Internal Data Request Form; which must be approved by the, BEMSTS Data & QA Section Chief, and BEMSTS Trauma Section Chief. See Exhibit 2.

G. Releasing Data to Independent Researchers.

1. Summary data may be released upon request.
2. Requests for confidential data must be approved by HSRB. (See Procedure B)

PROCEDURE

A. Preserving Confidentiality at the ASTR

1. All documents identifying a specific individual are considered confidential materials and, as such, are safeguarded to the maximum possible extent. Every employee having access to the ASTR has access to confidential information regarding persons with traumatic injuries and/or other medical conditions. It is the responsibility of each employee to protect the right of privacy of the persons whose records the ASTR maintains. This is a moral and legal obligation; therefore, rules of confidentiality are observed at all times.
2. Information that identifies a patient or the patient's family is not disclosed or discussed with anyone other than employees having access to ASTR or staff from specific reporting source(s). All employees are informed of their responsibility regarding confidential information. Breach of confidentiality will be grounds for immediate disciplinary action. All employees are required to sign a pledge to maintain confidentiality of all information.

B. Submitting a Request for Confidential Data for Research Purposes

1. The researcher may contact the ASTR by e-mail or by phone to announce his/her intent to submit a formal request. The Data & QA Section Chief or designee will fax or e-mail the "Public Records Request Form" (See ADM-020 Exhibit 1) and the ASTR "Arizona State Trauma Registry Data Request Form" (See Exhibit 3).
2. The researcher must complete the "Public Records Request Form" and the "Arizona State Trauma Registry Data Request Form" and fax or e-mail the forms to the ASTR.
3. The researcher must submit a request to the ADHS Human Subject Review Board (HSRB) for approval. No confidential data can be given to the researcher without prior approval of the HSRB. The HSRB application and instructions are available at <http://www.azdhs.gov/diro/legal/hsrb.htm>.
4. A copy of the formal request to the ADHS Human Subject Review Board must be forwarded to the Data & QA Section Chief. The formal request protocol should include:
 - a. A brief outline of the proposed research

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- b. A justification of the need for confidential data
- c. A list of requested data variables
- d. The preferred format of the data
- e. Needed frequency of the data (i.e., One-time data linkage vs. a continuous data pull for a survey)
- f. Description of how the data will be stored
- g. A list of who will have access to the data
- h. A description of how and when the data will be destroyed upon completion of the research project.
5. The checklist form "Checklist for Releasing Confidential Trauma Data" (See Exhibit 4) will be initiated to track progress of the request from submission to fulfillment or disapproval.
6. After review of the HSRB if approval is granted ASTR will be sent a copy of the letter of approval from HSRB. Upon receipt of the approval BEMSTS Chief, BEMSTS Medical Director, BEMSTS Data & QA Section Chief, BEMSTS Trauma Section Chief, and the Trauma Registry Manager will meet to determine whether participation with the researcher is appropriate.
 - a. Approval will not be granted to Researchers if the HSRB disapproves of the research project.
7. If an agreement is made to proceed with the research, the BEMSTS Data & QA Section Chief or designee will write a short memo documenting the decision and rationale for proceeding (i.e., the release is necessary for prevention) or disapproval. The Researcher will be notified if disapproved.
8. If approved the Trauma Registry Manager or the designated BEMSTS staff will complete the request.
9. Upon completion of the request, the ASTR will provide the researcher the confidential data file, a letter describing the data, and a data dictionary produced by the ASTR. These will be delivered via one of the following ways:
 - a. The requested variables in a password-protected CD-R in an ASCII fixed field length data file or agreed upon format through Fed Ex in an envelope marked "confidential".
 - b. The requested variables in a password-protected ASCII fixed field length data file or agreed upon format through encrypted e-mail using Secure Messenger by following the procedures in the Secure Messenger manual provided by Information Technology Services at ADHS.
 - c. The requested variables in a password-protected ASCII fixed field length data file or agreed upon format through encrypted secure File Transfer Protocol (FTP).
10. The password will be sent separately via an encrypted e-mail using Secure Messenger by following the procedures described in the Secure Messenger manual provided by Information Technology Services at ADHS.
11. The ASTR will maintain a patient listing of the data sent to the Researcher. This will allow the ASTR to answer any questions after the data file has been sent to the researcher. This also allows the ASTR to identify or track data used

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for research.

12. The ASTR will maintain all files related to the research project. The Trauma Registry Manager will update the Data Request Log immediately upon completion of the project.

Responsible Position: Data & QA Section Chief

C. Procedure for Data Linkage Using Confidential Data

1. Follow Procedure B.1-8 above; then proceed below.
2. ASTR or designated BEMSTS staff will be responsible for conducting the data linkage, providing the results to the researcher, and ensuring the confidentiality of the researcher's dataset.
3. The ASTR or designated BEMSTS staff will make arrangements with the researcher to perform the data linkage, including obtaining the data format and data variables that the researcher requires for the linkage. In most instances, it is preferred that the researcher provide the ASTR with a data set with which the ASTR can conduct the match; this method will restrict access to the ASTR records as much as possible. Some researchers may require the ASTR to provide them with a data set to which they can match their data.
4. The data file should be submitted on a CD-R in an ASCII fixed field length file or in an agreed upon format and exchange. The following variables should be included: first name, last name, social security number, date of birth, and sex.
 - a. Additional personal identifying information should also be included if available.
5. The data linkage will be completed using automated linkage:
 - a. For automated linkages, the ASTR will conduct a probabilistic match using LinkPlus. The match will be conducted on the fields listed in C.3. using a match probability of 95% or greater; a cut-off ratio will be determined at the time of linkage. The ASTR will make any necessary judgment calls as to whether possible matches contain enough information to be considered a match.
 - b. Matching records will be randomly reviewed to verify matched correctly.
6. The requested data on the matched cases will then be pulled from ASTR using the following process:
 - a. An export file of the matches is created in LinkPlus and MUST include the "Account Number" in addition to the fields that are being matched.
 - b. The Account Number will be used to pull from the ASTR program. In the ASTR program, an export file will be created containing the necessary patient identifiers, including the Account Number, and the requested variables. The procedure will be further defined in a separate Linkage procedure.
7. Upon completion of the data linkage and extract, the ASTR will provide to the researcher the data, a letter describing the data linkage procedures and criteria of release of registry data and a data dictionary. These will be delivered via one of the following ways:

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- a. The requested variables in a password-protected CD-R in an ASCII fixed field length data file or agreed upon format through Fed Ex in an envelope marked “confidential”.
- b. The requested variables in a password-protected ASCII fixed field length data file or agreed upon format through encrypted e-mail using Secure Messenger by following the procedures in the Secure Messenger manual provided by Information Technology Services at ADHS.
- c. The requested variables in a password-protected ASCII fixed field length data file or agreed upon format through encrypted secure File Transfer Protocol (FTP).
8. The password will be sent separately via an encrypted e-mail using Secure Messenger by following the procedures described in the Secure Messenger manual provided by Information Technology Services at ADHS.
9. It is anticipated that the linkage process described above will be completed within 6 weeks of receipt of the researcher’s data by the ASTR. The ASTR will notify the researchers of any delay in achieving this target date.
10. Data provided to the ASTR will be deleted from the ASTR computer system (and all copies and any derivatives files destroyed) as soon as the researcher notifies the ASTR in writing that the work scope has been completed.
 - a. There is one exception to all information that is destroyed after the process is complete. The ASTR will maintain the linked id number from the researcher file and the ASTR linked Account Number. This will allow the ASTR to answer any questions after the file has been sent to the researcher. This also allows the ASTR to identify or track data used for research.
11. The ASTR will maintain all forms, etc. related to research project. The Trauma Registry Manager will update the Data Request Log immediately upon completion of project.

Responsible Position: Data & QA Section Chief

D. Request for Non-confidential Aggregate Data

1. The person requesting the data will contact the ASTR by e-mail or by phone to announce his/her intent to submit a request. The Data & QA Section Chief or designee will fax or e-mail the ADHS form “Public Records Request Form” (See ADM-020 Exhibit 1) and the “Arizona State Trauma Registry Data Request Form” (See Exhibit 3).
 - a. The Trauma Registry Manager will ask the requestor to specify what data he/she is requesting on the form and to include his/her name, address, phone or e-mail information on the form so that the ASTR staff can contact him/her if necessary to complete the request.
2. The researcher must complete the “Public Records Request Form” and the “Arizona State Trauma Registry Data Request Form” and fax or e-mail the forms to the ASTR.
3. The Data & QA Section Chief or designee will review the request and contact the requestor when the written request is received to gather any additional information needed to fill the request.
 - a. The Data & QA Section Chief will estimate to the requestor when the data request may be completed.

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4. The Trauma Registry Manager runs the data query from the ASTR program. The Trauma Registry Manager will create summary data tables to send to the requestor. The Trauma Registry Manager will include the appropriate footnotes for the data query such as citing the ASTR as the data source, the date of the data query, and any other information specific to that data pull.
5. The Trauma Registry Manager e-mails or faxes the completed data request to the requestor. The Trauma Registry Manager fills out a data request cover sheet that includes the requestor's information, the data requested, and what information the Trauma Registry Manager gave the requestor, including the filenames and file locations of the data query. The data request cover sheet and any information related to this data request are stapled together and put in the data request file drawer. The Trauma Registry Manager will update the Data Request Log immediately upon completion of filling the request.
6. When filling data requests, the Trauma Registry Manager must use discretion and his/her best judgment to determine how much detailed information the ASTR can provide to the requestor. The Trauma Registry Manager must follow the ASTR confidentiality guidelines and the small numbers policy, if appropriate, set by the Bureau of Public Health Statistics. The ASTR is not permitted to give out any data that could lead to the identification of an individual.

Responsible Position: Data & QA Section Chief

E. Request for Non-confidential Patient Level Data

1. The person requesting the data will contact the ASTR by e-mail or by phone to announce his/her intent to submit a request. The Data & QA Section Chief or designee will fax or e-mail the ADHS form "Public Records Request Form" (See ADM-020 Exhibit 1) and the "Arizona State Trauma Registry Data Request Form" (See Exhibit 3).
 - a. The requestor is asked to specify what data he/she is requesting on the form and to include his/her name, address, phone or e-mail information on the form so that the ASTR staff can contact him/her if necessary to complete the request.
2. The researcher must complete the "Public Records Request Form" and the "Arizona State Trauma Registry Data Request Form" and fax or e-mail the forms to the ASTR.
3. After reviewing the request, the Data & QA Section Chief or designee will contact the requestor when the written request is received and gather any additional information needed to fill the request.
 - a. The Data & QA Section Chief will determine if this request can be done and that it does not violate confidentiality procedures. If there are questions related to appropriateness of releasing patient level data the BEMSTS Chief, BEMSTS Data & QA Section Chief and the BEMSTS Trauma Section Chief will make the final determination.
 - b. The Data & QA Section Chief will estimate to the requestor when the data request may be completed.
4. If an agreement is made to proceed with the release of patient-level non-confidential data, the Data & QA Section Chief will write a short memo documenting the decision to proceed. The Trauma Registry Manager will fax or e-mail the ASTR "Public-Use Data Agreement" form (See Exhibit 1) to the requestor to complete. If the request is disapproved, the Data & QA Section Chief will notify the requestor.

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5. The Trauma Registry Manager will process the request.
6. Upon completion of the data request, the ASTR will send the data to the requestor with the requested variables and a data dictionary. These will be delivered via one of the following ways:
 - a. The requested variables in a password-protected CD-R in an ASCII fixed field length data file or agreed upon format through Fed Ex in an envelope marked “confidential”.
 - b. In a password-protected ASCII fixed field length data file or agreed upon format through encrypted e-mail using Secure Messenger by following the procedures in the Secure Messenger manual provided by Information Technology Services at ADHS.
 - c. In a password-protected ASCII fixed field length data file or agreed upon format through encrypted secure File Transfer Protocol (FTP).
7. The password will be sent separately via an encrypted e-mail using Secure Messenger by following the procedures described in the Secure Messenger manual provided by Information Technology Services at ADHS.
8. The ASTR will maintain all forms , etc. related to the data request. The Trauma Registry Manager will update the Data Request Log immediately upon completion of project.

Responsible Position: Data & QA Section Chief

F. Request for Non-Confidential Public Use File for Research Purposes

1. The researcher requesting the data will contact the ASTR by e-mail or by phone to announce his/her intent to submit a request. The Data & QA Section Chief or designee will fax or e-mail the ADHS form “Public Records Request Form” (See ADM-020 Exhibit 1) and the “Arizona State Trauma Registry Data Request Form” (See Exhibit 3).
 - a. The Researcher will be asked to specify what data he/she is requesting on the form and to include his/her name, address, phone or e-mail information on the form so that the ASTR staff can contact him/her if necessary to complete the request.
2. The researcher must complete the “Public Records Request Form” and the “Arizona State Trauma Registry Data Request Form” and fax or e-mail the forms to the ASTR.
3. The researcher must submit a formal request protocol to the ASTR. The request should include:
 - a. A brief outline of the proposed research
 - b. A justification of the need for the Public Use File
 - c. A list of necessary data variables for the research
 - d. The preferred format of the data
 - e. Needed frequency of the data (i.e., One-time data linkage vs. a continuous data pull for a survey)

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- f. Description of how the data will be stored
- g. A list of who will have access to the data
- h. A description of how and when the data will be destroyed upon completion of the research project.
4. The Data & QA Section Chief or designee will, after reviewing the request, contact the requestor when the written request is received in order to gather any additional information needed to fill the request.
5. The BEMSTS Chief, BEMSTS Medical Director, BEMSTS Data & QA Section Chief, BEMSTS Trauma Section Chief, and the Trauma Registry Manager will meet to determine whether the use of a Public Use Data File is appropriate.
6. If an agreement is made to proceed with the release of patient-level non-confidential data, the Data & QA Section Chief will write a short memo documenting the decision to proceed. The ASTR "Public-Use Data Agreement" form (See Exhibit 1) will be sent to the Researcher to complete. The Data & QA Section Chief will notify the researcher if the request is disapproved.
7. The Trauma Registry Manager or the designated BEMSTS staff will run the request.
- a. The Data & QA Section Chief or designee will estimate to the researcher when the data request may be completed.
8. Upon completion of creating the Public Use File, the ASTR will provide to the researcher the data and a data dictionary. These will be delivered via one of the following ways:
 - a. The requested variables in a password-protected CD-R in an ASCII fixed field length data file or agreed upon format through Fed Ex in an envelope marked "confidential".
 - b. In a password-protected ASCII fixed field length data file or agreed upon format through encrypted e-mail using Secure Messenger by following the procedures in the Secure Messenger manual provided by Information Technology Services at ADHS.
 - c. In a password-protected ASCII fixed field length data file or agreed upon format through encrypted secure File Transfer Protocol (FTP).
9. The password will be sent separately via an encrypted e-mail using Secure Messenger by following the procedures described in the Secure Messenger manual provided by Information Technology Services at ADHS.
10. The ASTR will maintain all forms, etc. related to data request. The Trauma Registry Manager will update the Data Request Log immediately upon completion of project.

Responsible Position: Data & QA Section Chief

G. Request for Non-confidential Patient Level Data by ADHS Staff

1. To submit a formal request for non-confidential patient data, the ADHS staff member must fill out a Release of Data

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Internal Request form (See Exhibit 2) and send it to the Data & QA Section Chief. The request should include:

- a. The preferred format of the data, the frequency that they need this data (i.e. a one-time data linkage vs. a continuous data pull for a survey) needs to be stated on the form.
 - b. A brief outline of the proposed use of the data
 - c. A justification of need for patient level data
 - d. A list of data variables requested.
2. The request will be reviewed by the BEMSTS Chief, BEMSTS Data & QA Section Chief and the BEMSTS Trauma Section Chief.
 3. If the request is approved, the Trauma Registry Manager runs the data query from the ASTR program and exports all records meeting the requestor's criteria with requested data fields into an ASCII fixed field length text file or agreed upon format.
 4. The data is sent to the internal staff by either intranet e-mail or a CD.
 5. If the request is rejected, the Trauma Registry Manager e-mails the requestor stating reasons for request rejection and indicates changes needed in request for it to be approved.
 6. The ASTR will maintain all forms, etc. related to data request. The Trauma Registry Manager will update the Data Request Log immediately upon completion of project.

Responsible Position: Data & Quality Assurance Section Chief

<u>Approved:</u> <hr/> Joel Bunis, Data & Quality Assurance Section Chief <hr/> Vicki Conditt RN, BEMSTS Trauma Section Chief	<u>Date:</u> <hr/>
The Division of Primary Responsibility for this policy is the Bureau of EMS & Trauma System. Users are encouraged to suggest improvements regarding this policy and procedure.	